

**IN THE UNITED STATES DISTRICT COURT FOR THE
MIDDLE DISTRICT OF TENNESSEE
NASHVILLE DIVISION**

RUTH SMITH, Individually and as Widow)	
for the Use and Benefit of Herself and the)	
Next of Kin of RICHARD SMITH, Deceased,)	Case #: 3:05-00444
)	Judge Trauger
Plaintiff,)	
)	
-against-)	
)	
PFIZER INC., PARKE-DAVIS,)	
a division of Warner-Lambert Company)	
and Warner-Lambert Company LLC,)	
WARNER-LAMBERT COMPANY,)	
WARNER-LAMBERT COMPANY LLC and)	
JOHN DOE(S) 1-10,)	
)	
Defendants.)	

**PLAINTIFF’S MEMORANDUM IN OPPOSITION TO DEFENDANTS’
MOTION *IN LIMINE* TO EXCLUDE EVIDENCE OF MARKETING OR
ADVERTISING MATERIALS AND CONDUCT AND OTHER LITIGATIONS**

Plaintiff Ruth Smith, as the Widow for the use and benefit of herself and the next of kin of Richard Smith, deceased, by and through her attorneys, respectfully requests that this Court deny in its entirety Defendants’ motion *in limine* to exclude evidence of marketing or advertising materials and conduct and other litigations on the grounds that: (1) pursuant to Fed. R. Evid. 401, such information is relevant to various salient issues in this litigation, including Defendants’ negligence, failure-to-warn, suppression, and recklessness in not demonstrating the safety of Neurontin in off-label populations as to whom the company had notice were using Neurontin; (2) these materials demonstrate Defendants’ negligence in knowingly and recklessly promoting Neurontin to off-label populations without performing the adequate pharmacovigilance to ascertain whether Neurontin was safe for such uses; (3) these materials show that Defendants had full knowledge of the extent of off-label use of Neurontin, that Defendants did not know whether

the product was safe for use in those off-label populations, and that Defendants were negligent and reckless in not taking adequate steps to learn of the safety in these populations; (4) Defendants' negligence in each case flows from the same facts and circumstances in regard to the issue of Defendants' breach of care; (5) Defendants received additional knowledge from the filing of lawsuits that there were safety concerns and instead chose to sit on their hands rather than perform the required pharmacovigilance is further evidence of their reckless disregard for the safety of the off-label population; and (6) the probative value of the evidence at issue greatly outweighs any potential unfair prejudice to Defendants.

INTRODUCTION

On June 5, 2009, Judge Patti B. Saris in the multidistrict litigation, *In re Neurontin Marketing, Sales Practices & Products Liability Litigation*, 1:04-cv-10981-PBS (D. Mass), issued an Electronic Order relating to a similar motion interposed by Defendants, and denied Defendants' request to remove evidence related to national marketing. On June 22, 2009, Defendants again moved to exclude evidence of marketing or advertising in the MDL, in *Bulger v. Pfizer Inc.*, which motion Judge Saris denied by an Electronic Order on July 24, 2009.

ARGUMENT

POINT I

PLAINTIFF'S USE OF NATIONAL MARKETING OR ADVERTISING OF DEFENDANTS' OFF-LABEL PROMOTION OF NEURONTIN IS PROPER BECAUSE SUCH EVIDENCE IS RELEVANT TO PLAINTIFF'S CLAIMS THAT DEFENDANTS BREACHED THEIR DUTY OF CARE, INCLUDING PERFORMING ADEQUATE PHARMACOVIGILANCE, AND PUNITIVE DAMAGES

"Relevant evidence" means evidence having any tendency to make the existence of any fact that is of consequence to the determination of the action more probable or less probable than it would be without the evidence." Moore's Fed. Rules Pamphlet 2009, Fed. R. Evid. 401.

Defendants' national marketing documents relating to off-label marketing are admissible at trial to the extent they are relevant to Plaintiff's negligence, failure-to-warn, and negligent pharmacovigilance claims against Defendants. *See In re Neurontin Mktg., Sales Practices & Prods. Liab. Litig.*, 618 F. Supp. 2d 96, 114 (D. Mass. 2009).

Judge Saris succinctly described the heightened duty to warn that a pharmaceutical manufacturer bears when it engages in off-label marketing of a drug:

Based on the reasoning of this caselaw, the Court concludes that a manufacturer of a pharmaceutical has a duty to disclose to physicians and patients material facts about the risks of the drug, particularly when it is engaged in off-label marketing for uses not approved by the FDA, if it knows that the plaintiff and/or his prescriber does not know or cannot reasonably discover the undisclosed facts.

Id. at 110 (emphasis added).

The manufacturer's knowledge of off-label use with its drug is inextricably intertwined with a manufacturer's duty to disclose material facts about risks with the drug. While off-label prescribing by physicians is not itself improper, a manufacturer with knowledge of both extensive off-label use and material facts about risks inherent with taking the drug (e.g., depression and suicide), has a duty to take action. As explained below, Defendants were on notice both of the risks of depression and of the substantial off-label use of Neurontin. Defendants' national marketing documents are probative of Defendants' negligence.

First, Defendants' marketing documents are relevant to Plaintiff's proof that Defendants had a regulatory duty to create, establish and execute a pharmacovigilance plan to evaluate and analyze suicide and depression adverse events. Defendants were on notice of risks since at least 1992. The FDA stated at that time: "Less common but more serious events may limit the drug's widespread usefulness . . . [D]epression, while it may not be an infrequent occurrence in the

epileptic population, may become worse and require intervention or lead to suicide, as it has resulted in some suicidal attempts.” *Id.* at 102 (emphasis added).

Defendants knew of Neurontin’s subsequent widespread off-label use. Sales of Neurontin for off-label uses were at approximately 90% before Richard Smith’s death. *Id.* at 104. Central to Plaintiff’s cause of action is to establish when the duty to take action through warning and enhanced pharmacovigilance arose. Plaintiff intends to prove that duty arose when the off-label use of Neurontin substantially increased. Plaintiff intends to use the national marketing documents to establish when Defendants should have undertaken to create a pharmacovigilance plan. Defendants’ negligent actions continued at least through 2004 (subsequent to the time that Richard Smith died), when Pfizer Defendants (not just the Parke-Davis and Warner-Lambert entities) failed to recognize and fully disclose suicide risks with Neurontin and, instead, sought to compare Neurontin as safer than competing drugs that did have specific warnings related to suicide. *See* Declaration of Kenneth B. Fromson, Ex. A at 27; *In re Neurontin*, 618 F. Supp. 2d at 103.

Second, not only did Defendants know of the widespread off-label use of Neurontin — indeed they engaged in off-label promotion — Defendants were on notice that patients using Neurontin for off-label uses were at risk. Separate and apart from the FDA’s concern in 1992, the risk was confirmed by Defendants’ pharmacovigilance witness, Manfred Hauben, whose internal Pfizer documents included the following salient language:

With the post marketing use of gabapentin in patients other than with epilepsy, it is important to identify whether these new populations may be particularly susceptible to specific adverse drug effects, both labeled and unlabeled, and to identify conditions under which specific adverse events may be more likely to occur in these new patient populations.

Fromson Decl., Ex. B.

It is axiomatic that Defendants had a duty to apply this knowledge about Neurontin's off-label usage to research the risks of suicidality, which Defendants negligently chose not to undertake. Instead of researching and investigating the safety of Neurontin when used in off-label populations that were particularly susceptible to specific adverse drug effects, Defendants negligently promoted Neurontin for off-label uses not approved by the FDA including "pain", the indication for which Richard Smith was prescribed Neurontin. *Id.* at 5; *see* Fromson Decl., Ex. C. Not until 2006 did Defendants' own Risk Management Strategy Department implement a purported investigation of suicidality (i.e., the Gabapentin Data Capture Aid). *See* Fromson Decl., Ex. D. In sum, central to Plaintiff's cause of action is to establish when the duty to take action through warning and enhanced pharmacovigilance arose. Plaintiff intends to prove that the duty arose with known substantial increase of off-label use of Neurontin. Defendants' knowledge is established through the national marketing documents.

Applying the language and reasoning of Judge Saris, for purposes of Plaintiff's negligence claims, Plaintiff shall pursue at trial the foundational evidence that Defendants "engaged in off-label marketing" and thus had a "particular[]" "duty to disclose to physicians and patients material facts about the risks of [Neurontin]." *See In re Neurontin*, 618 F. Supp. 2d at 110. Defendants were negligent and breached their duty of care to Plaintiff's decedent, Richard Smith, by failing to adequately warn about the increased risk of suicidality with Neurontin ingestion, particularly where Defendants had knowledge of the substantial off-label use with Neurontin. Defendants' knowledge of substantial off-label use and subsequent failure to warn of suicidality proximately caused Richard Smith to commit suicide.

Defendants' actions in seeking to preclude all evidence related to national marketing blatantly disregards that such documents and witness designations are probative of matters other

than fraud. Defendants seek to expand improperly upon Judge Saris' decision of May 26, 2009, *In re Neurontin*, 618 F. Supp. 2d 96, relating the limitation of evidence on Defendants' national marketing campaign and Plaintiff's fraudulent concealment claims. The cases cited by Defendants are quite distinguishable from the situation here where Plaintiff will proffer national marketing evidence to demonstrate Defendants' breach of duty and negligence. *In re Norplant Contraceptive Prods. Liab. Litig.*, MDL No. 1038, 1997 U.S. Dist. LEXIS 11091 (E.D. Tex. Feb. 21, 1997), involved FDA-approved direct-to-consumer advertising and the issue of dilution of the warning, not a manufacturer's use of a marketing campaign for off-label uses to circumvent the FDA approval process and failure to provide adequate warnings regarding the risk of suicide. In *In re Seroquel Prods. Liab. Litig.*, No. 6:06-md-1769-Orl-22DAB, 2009 WL 223140, 2009 U.S. Dist. LEXIS 124798 (M.D. Fla. Jan. 30, 2009), plaintiff was going to utilize the promotional materials in regard to their claims of omission and misrepresentation. Defendants' citation to *Miller v. Pfizer Inc.*, 196 F. Supp. 2d 1095 (D. Kan. 2002), refers to a plaintiff's assertion that a physician had subliminally received the manufacturer's fraudulent marketing message, and the court granted defendants' summary judgment on their fraud based claims. But here, Plaintiff is not utilizing the documents to demonstrate fraud or dilution of the warning in this case, but is using the documents to demonstrate Defendants' intentional breach of their common law and statutory duty of care.

Moreover, Plaintiff's decedent's prescribing physician, Dr. Edward Mackey, testified that he was not aware of various important information concerning problems with Neurontin, depression and suicide, and that had he been told of these problems with Neurontin, he "[c]ertainly" would have given Mr. Smith specific warnings and told him to be observant about side effects; and Nurse Krancer testified that had Defendants told her that Neurontin was

associated with increases in depression and suicide, she would have educated the patients on these potential side effects. *See* MDL Docket No. 1678, Further Statement, ¶¶ 15-23, re Learned Intermediary. Mr. Smith's prescribing medical providers, Dr. Paul McCombs and Dr. Mackey, testified about the material information suppressed by Defendants. Both doctors, in discussing their prescribing practices and risk/benefit analyses for prescribing a drug to Mr. Smith, wanted to know about suicide attempts during clinical trials; depression adverse events during clinical trials, and whether depression and suicidality were side effects. MDL Docket No. 1679, Ex. 11 at 12:3-12:19, 12:20-14:23, 28:10-29:19; MDL Docket No. 1679, Ex. 12 at 34:14-36:25.

Defendants' actions in breaching their duty of care and failing to perform adequate pharmacovigilance that inevitably led to the failure to warn that Neurontin causes adverse mood and behavior changes and increases the risk for suicidality, resulted in preventing Richard Smith and his prescribing physician(s) from being able to fully assess the risk-benefit analysis for the underlying off-label condition for which Neurontin was prescribed to Mr. Smith, and from being able to fully monitor changes in his mood and behavior caused by Neurontin.

POINT II

PLAINTIFF'S USE OF DEFENDANTS' NATIONAL MARKETING AND ADVERTISING FOR THE OFF-LABEL PROMOTION OF NEURONTIN IS PROPER BECAUSE SUCH EVIDENCE IS RELEVANT TO DEFENDANTS', INCLUDING PFIZER'S, INTENTIONAL AND RECKLESS PROMOTION OF THEIR DRUG NEURONTIN TO OFF-LABEL POPULATIONS WITHOUT PERFORMING THE ADEQUATE PHARMACOVIGILANCE TO ASCERTAIN WHETHER NEURONTIN WAS SAFE FOR SUCH USES

Defendants argue that the marketing evidence is not relevant to the question of duty of care because "the *risk* was unforeseeable." Defs. Mem., Docket No. 116 at 6. What is perfectly clear is that Defendants were negligent and reckless in knowingly not performing adequate pharmacovigilance to ascertain whether the drug was safe for the off-label uses by the population

for which they were promoting the drug off-label. According the law of this case, Defendants have a heightened duty of care when promoting the drug for off-label uses, uses not approved by the FDA. *In re Neurontin*, 618 F. Supp. 2d at 110. Plaintiff requires the national marketing documents to demonstrate that Defendants were negligent and reckless when they knowingly disregarded the safety of the off-label population taking Neurontin, by not performing the requisite pharmacovigilance, while promoting Neurontin for off-label uses. Even absent direct promotion, the company was well aware of the extent of the off-label use and that it did not know whether the product was safe for use in those populations.

Moreover, Pfizer itself is complicit in this failure and perpetuated the breach of duty and negligence when they took control of the manufacture of Neurontin. An April 1, 2003 e-mail by Defendants' employee John Marino demonstrates that after Pfizer took control of Warner-Lambert, Pfizer was well aware that Neurontin was only approved for epilepsy yet boasted of sales well in excess of that which was anticipated (an in excess of the adjunctive epileptic drug marketplace) and noted that there were "lots of legal problems." Fromson Decl., Ex. E. The e-mail shows that Pfizer, instead of performing the required pharmacovigilance so that it could apply for FDA approval for the off-label indications, knowingly sat on their hands and sought to just continue to reap the profits from the illegal off-label marketing boon.

Moreover, in December 2000, although Pfizer Defendants were concerned with legal challenges in regard to prior off-label practices to illegally promote Neurontin and were going to refrain from same, Pfizer knowingly did nothing to ascertain the risks of the Neurontin to off-label users — they failed to evince any concern regarding the safety of the drug, which had not been properly tested or approved by the FDA for these off-label uses. Fromson Decl., Ex. F. Further, contrary to Defendants' assertions that "the risk was unforeseeable," the chart, entitled

“Percentage of Serious Reports For Suicide and Self injurious Behavior,” prepared by Plaintiff from data extracted from the Neurontin Adverse Event Database, indicates that as of June 30, 1999, there were indications that there was an increased risk for suicide for off-label indications.¹ Fromson Decl., Ex. G. Defendants’ duty of care was to ascertain the risks, and the risks were apparent, but Defendants simply made an **intentional** decision to sit on their hands and not perform the adequate pharmacovigilance. The marketing documents demonstrate the negligence of Defendants, both Warner-Lambert and Pfizer, and their reckless disregard for the safety of the off-label population to whom they were either actively promoting the drug illegally or sitting idle and reaping the benefits of the off-label promotion, without performing the required pharmacovigilance to assess the risks to this population.

POINT III

THE NATIONAL MARKETING DOCUMENTS ARE RELEVANT TO SALIENT ISSUES IN THIS CASE AND PLAINTIFF WILL BE SEVERELY PREJUDICED IF THE DOCUMENTS ARE EXCLUDED; THE PROBATIVE VALUE OF THE DOCUMENTS SUBSTANTIALLY OUTWEIGHS ANY POTENTIAL FOR UNFAIR PREJUDICE, WILL NOT CONFUSE THE ISSUES OR WASTE THE COURT’S TIME, AND PLAINTIFF DOES NOT SEEK TO INTRODUCE SAME AS EVIDENCE OF DEFENDANTS’ BAD ACTS — THE NATIONAL MARKETING DOCUMENTS ARE NOT PRIOR ACTS FROM ANOTHER LITIGATION BUT DEFENDANTS’ ACTS FORM THE FACTS AND CIRCUMSTANCES OF THEIR NEGLIGENCE IN THIS LITIGATION

To be admissible, evidence must be relevant. Fed. R. Evid. 401. Relevant evidence is defined as evidence which may tend to prove or disprove a material fact that is of consequence to

¹ Although Defendants’ Memorandum cites to caselaw insinuating that Defendants could not have known of the risks (Docket No. 116 at 5, 6), Judge Saris has recognized that Plaintiffs sufficiently countered that misplaced argument in their opposition briefing, D. Mass. No. 1:04-cv-10981-PBS, Docket No. 1197, to Defendants’ *Daubert* and summary judgment briefing. See *In re Neurontin Mktg., Sales Practices & Prods. Liab. Litig.*, 612 F. Supp. 2d 116, 153-57 (D. Mass. 2009). Judge Saris specifically stated: “In fact, when hired by Warner-Lambert to investigate the relationship between gabapentin and behavioral disturbances in the mid-1990s, Dr. Trimble (now one of Plaintiffs’ experts) advised the company that one of the strongest associations with anticonvulsant drugs generally was to depression. (Trimble Rep. 29; see Michael Trimble, *Psychosis with Gabapentin (Neurontin)*, May 20, 1995), Pls.’ Ex. 17.)” *Id.* at 129.

the determination of the action.. Fed. R. Evid. 401. Further, “relevant evidence may be excluded if its probative value is substantially outweighed by the risk of (a) undue prejudice, confusion of issues, or misleading the jury or (b) undue delay, waste of time, or needless presentation of cumulative evidence.” Fed. R. Evid. 403 (emphasis added). It is clear that “all relevant evidence is to some degree prejudicial. What the rule discourages is unfair prejudice, which is evidence that has ‘an undue tendency to suggest decision on an improper basis, commonly but not necessarily an emotional one.’” *Donathan v. Orthopaedic & Sports Medicine Clinic, PLLC*, No. 4:07-cv-18, 2009 U.S. Dist. LEXIS 99557 at *7 (E.D. Tenn. Oct. 26, 2009) (citing to *United States v. Whittington*, 455 F.3d 736, 739 (6th Cir. 2006). In its determination whether evidence should be excluded under Rule 403, “the court should ‘give the evidence its maximum reasonable probative force and its minimum reasonable prejudicial value.’” *Id.* (citations omitted). Plaintiff is seeking that the marketing documents be admitted for a wholly permissible purpose: to prove Defendants’ breach of duty, negligence and their intentional disregard for the safety of off-label users of Neurontin.

The Sixth Circuit has stated that Fed. R. Evid. 404(b) “is actually a rule of inclusion rather than exclusion, since only on use if forbidden and several permissible uses of such evidence are identified. The list of permissible uses is not exclusive. Courts have recognized other permissible uses of such evidence; for example, to show a common scheme or plan.” *United States v. Blankenship*, 775 F.2d 735, 739 (6th Cir. 1985). Evidence must meet the threshold of relevance, “that is, the evidence must relate to a matter which is “in issue” and must deal with conduct substantially similar and reasonably near in time”. *Id.* In *United States v. Barnes*, the Sixth Circuit made it perfectly clear that “intrinsic” acts or evidence do not implicate Fed. R. Evid. 404(b). 49 F.3d 1144, 1149 (6th Cir. 1995). The Sixth Circuit defined “intrinsic”

acts as “those that are part of a single criminal episode. Rule 404(b) is not implicated when the other crimes or wrongs evidence is part of a continuing pattern of illegal activity.” *Id.* The Court affirmed the defendants’ convictions for drug trafficking, and the trial court’s ruling that evidence consisting of testimony that the defendant was expecting to pick up another package of illegal drugs on the date of his arrest while picking up a package of illegal drugs was evidence that “was intrinsically related” to the acts at issue and “that the evidence was admissible under Rule 404(b).” *Id.* at 1145.

Initially, to make it perfectly clear, the facts are what the **facts are in this case** — these are not allegations or prior bad acts from an unrelated prior case or drug litigation — Defendants pled guilty to illegally promoting Neurontin for off-label uses, **they intentionally failed to perform the adequate pharmacovigilance even though they were aware of the risks for the off label uses which relegated Neurontin unsafe for off label uses in this litigation.** Furthermore, as part of the guilty plea, Defendants admitted that the package inserts lacked adequate directions for use in off label indications, such as Plaintiff in this case. Plaintiff submits that the national marketing documents is intrinsic evidence that are part and parcel of Defendants’ illegal activity for the off-label promotion of Neurontin without first performing the requisite safety studies for those indications — part of a continuing pattern of criminal activity and therefore not the subject of a 404(b) objection to admissibility. It is rather troubling that Defendants allege that Plaintiffs will utilize the marketing materials to encourage jurors to base their decision on “inflammatory allegations against Pfizer.” Plaintiff intends to use the national marketing documents to demonstrate conduct that directly affected Plaintiff and that Defendants’ assertion that these documents demonstrate prior bad facts is simply wrong. What is clear that any advertising of the product through the time of Mr. Smith’s death failed to include the very

risks that are at the heart of this case — that of suicidal and self injurious behavior. Defendants are playing with words and being cavalier in their terminology and not accepting any responsibility for their illegal actions which is the cause and at the **forefront in this litigation**. Plaintiff is going to utilize the marketing documents, part of the very facts and circumstances which formed this litigation, to demonstrate Defendants’ breach of the duty of care and negligence. “All relevant evidence is to some degree prejudicial” and so unfair prejudice does not mean “no prejudice” at all, as noted in *Donathan* , *supra*.

As explored in detail above, Plaintiff seeks to introduce the national marketing documents for salient issues in this case — Defendants’ breach of their duty of care and their negligence and knowing and reckless disregard for the safety of the off-label population to whom Defendants marketed the drugs without performing the requisite pharmacovigilance or receiving FDA approval. Not only do the national marketing documents demonstrate Defendants’ intent to breach their duty of care, the national documents actually show a plan and scheme to circumvent the pharmacovigilance requirements of the FDA and, instead, promote the drugs off-label for uses not approved by the FDA. The documents also demonstrate the continuing practice of suppressing material information on the safety of Neurontin. These issues are critical in this case, and Plaintiff will be severely prejudiced if she is not permitted to introduce this evidence to prove her claims. Defendants did not perform adequate pharmacovigilance for these drugs to ascertain the safety for off-label users. Both of these facts go to proving Defendants’ breach of duty of care and negligence. Defendants can, and probably will, claim that any evidence that Plaintiff wishes to proffer in this case will be prejudicial. But admitting the national marketing documents for the proper purpose — to demonstrate negligence and duty — will not cause

Defendants unfair prejudice for the actions that they intentionally took in relation to off-label uses of Neurontin.

On the other hand, the probative values of these documents substantially outweigh any potential prejudice to Defendants. Plaintiff will suffer severe prejudice if she is unable to utilize the national documents to show Defendants' negligence and breach of duty of care. Plaintiff's claim for the breach of duty and her negligence claim is fairly straightforward, and Plaintiff's use of the national marketing documents will not confuse the jury.

POINT IV

DEFENDANTS' BREACH OF THEIR DUTY OF CARE AND THEIR RECKLESS INDIFFERENCE TO THE SAFETY OF OFF-LABEL USERS OF NEURONTIN AS DEMONSTRATED BY THE NATIONAL MARKETING DOCUMENTS AND TESTIMONY, ETC., ARE PROPERLY EVIDENCE FOR THE ISSUE OF PUNITIVE DAMAGES

Once again, Defendants are citing to caselaw that is inapposite and does not apply in this case — they reference instances where the facts and circumstances of the lawsuits are not related to the case at hand or improperly based on prior unrelated lawsuits. In direct contrast, in this situation, the other claims and lawsuits in question all emanate from the same breach of Defendants' duty of care and will be utilized to demonstrate notice — not punishment. As noted in detail above, what is perfectly clear is that Defendants were negligent and reckless in knowingly not performing adequate pharmacovigilance to ascertain whether the drug was safe for the off-label uses by the population for which they were promoting the drug off-label, and their breach, which is demonstrated by the national marketing documents, harmed and caused the death of Richard Smith.

The Supreme Court of Tennessee stated in *Flax v. DaimlerChrysler Corp.*, in regard to the standard for punitive damages:

A verdict imposing punitive damages must be supported by clear and convincing evidence that the defendant acted intentionally, fraudulently, maliciously, or recklessly. *Hodges v. S.C. Roff & Co.*, 833 S.W.2d 896, 901 (Tenn. 1992). In *Hodges*, we held that evidence is clear and convincing when it leaves "no serious or substantial doubt about the correctness of the conclusions drawn." *Id.* at 901 n.3. We also held that a person acts recklessly when "the person is aware of, but consciously disregards, a substantial and unjustifiable risk of such a nature that its disregard constitutes a gross deviation from the standard of care that an ordinary person would exercise under all the circumstances." *Id.* at 901. The jury in this case found that there was clear and convincing evidence that DCC's conduct was reckless.

272 S.W.3d 521, 531 (Tenn. 2008).

In *United States v. Fraser*, the Sixth Circuit affirmed the judgment of the district court and the admission into evidence portions of a book which described the illegal scheme and was written by the defendant prior to commission of the charged crime on the grounds that the evidence served to demonstrate his "intent." 448 F.3d 833, 835 (6th Cir. 2006). The Sixth Circuit found that because the defendant has stated that he was "duped," he placed his intent at issue, but noted that "there was no obligation to wait and see whether the defendant argues the nonexistence of an element of crime" before proffering evidence to establish the specific element." *Id.* at 839.

Plaintiff requires the national marketing documents to demonstrate that Defendants were malicious, willful, wanton or reckless when they knowingly disregarded the safety of Richard Smith, an off-label user, to risks, **about which Defendants were aware but did not warn**, and thereby intentionally breached their duty of care in promoting Neurontin for such an off-label use rather than performing pharmacovigilance. Defendants' intentional and reckless conduct is intertwined and directly related, and not independent, with their breach of their duty of care for which Plaintiff claims that Defendants are liable for the injuries and death sustained by Richard Smith in this case. Although Defendants aver that the risks were unforeseeable, Defendants

knew that the clinical review for Neurontin had stated that depression was an issue with Neurontin that would limit the usefulness of the drug for other indications. Furthermore, Defendants were aware that suicide could be risk of specific off label populations and that it was necessary to evaluate this risk. Fromson Decl., Ex. B. Instead of performing the requisite safety studies for the off-label uses — unapproved by the FDA, Defendants embarked on an elaborate illegal marketing plan for off-label uses. Plaintiff is using the national marketing documents or other litigations as evidence to demonstrate that Defendants had knowledge of the risks of increased suicidality and that, instead of performing the pharmacovigilance required, intentionally breached their duty of care by sitting on their hands and not warning Richard Smith and his prescribers of such risks. This is the conduct that is reprehensible and for which punitive damages should be considered.

POINT V

THE MARKETING DOCUMENTS ARE RELEVANT TO PLAINTIFF'S CLAIMS THAT DEFENDANTS' FRAUDULENTLY CONCEALED AND/OR SUPPRESSED THE RISKS FOR ADVERSE MOOD AND BEHAVIOR CHANGES AND THE INCREASED RISK FOR SUICIDE FROM THE INGESTION OF NEURONTIN FROM RICHARD SMITH AND HIS PRESCRIBING PHYSICIANS

Defendants actively promoted Neurontin to Mr. Smith's prescribing medical providers via direct sales representative detailing to the doctors' offices. MDL Docket No. 1679, Ex. 13. Nothing in the record reflects that any of Defendants' sales representatives informed Mr. Smith's prescribing medical providers of Neurontin's association with depression/suicidality. Furthermore, it is clear that whenever a sales representative provided samples or other materials, Neurontin's risk of suicidal and self injurious behavior was not included in the labeling accompanying these materials. But it is known that the providers were detailed, and Mr. Smith was prescribed Neurontin for pain — an off-label, unapproved use. MDL Docket No. 1679, Ex.

12 at 28:14-28:19. In fact, although Defendants acknowledge it was inappropriate to detail physicians other than neurologists and epileptologists (MDL Docket No. 1679, Ex. 14 at 45:8-45:25; *see* MDL Docket No. 1679, Ex. 15 at 009942), Defendants detailed Mr. Smith's neurosurgeon, an orthopedist, and a nurse. In doing so, Defendants, who breached their own internal standards, fraudulently misrepresented to Mr. Smith's prescribing physicians that Neurontin was safe and/or efficacious for indications never approved for use by the FDA (i.e., pain and neuropathic pain).

For example, prior to Mr. Smith's death, Defendants' sales representative actively promoted Neurontin to Mr. Smith's orthopedist, Dr. Mackey, and the doctors in his medical practice on approximately 69 occasions with respect to Neurontin. MDL Docket No. 1679, Ex. 16. Dr. Mackey testified that Defendants detailed him about "neuropathic pain," which is an off-label, unapproved use by the FDA. MDL Docket No. 1679, Ex. 12 at 76:23-77:16.

Defendants' sales representative actively promoted Neurontin to Mr. Smith's healthcare provider, Nurse Pamela Krancer, on approximately 27 occasions with respect to Neurontin. Defendants' sales representative Ashley Pippin planned to "probe" into where Nurse Krancer was dispensing Neurontin and "get help through her with other surgeons." MDL Docket No. 1679, Ex. 17. Defendants' sales representatives clearly acted on this "probe" plan as evidenced by the more than 300 occasions in which Defendants detailed the medical practice and distributed Neurontin samples² to the medical practice where both Mr. Smith sought treatment and Nurse Krancer worked. MDL Docket No. 1679, Ex. 18.

Defendants' sales representative also detailed Dr. McCombs, a neurosurgeon, on

² Noteworthy, each distribution of a Neurontin sample to the medical practice also included the Neurontin Label which Defendants admit provided inadequate directions for unapproved uses. This admission is reflected in their 2004 guilty plea for distributing a misbranded drug. *See* MDL Docket No. 1200-3, Ex. 2.

approximately three occasions with respect to Neurontin. MDL Docket No. 1679, Ex. 19.

Dr. Mackey acknowledged that his understanding of Neurontin's off-label use to treat Dr. Smith's pain was in part based upon his interactions with other doctors in his practice. MDL Docket No. 1679, Ex. 12 at 27:6-27:13. Dr. Mackey subscribed to journals and he consulted physicians outside of his practice as well as with his two partners — neither of whom were neurologists or epileptologists — but both had been detailed extensively by Defendants about Neurontin for off-label uses. MDL Docket No. 1679, Ex. 16; Ex. 12 at 28:20-31:25, 74:1-74:23. Dr. Mackey acknowledged that he utilized the Physician's Desk Reference, which would have included the Neurontin label, for his risk/benefit analysis before prescribing a drug. MDL Docket No. 1279, Ex. 12 at 73:12-73:25. Dr. Mackey also testified that he had been detailed by Defendants' sales representative regarding Neurontin, who discussed Neurontin usage and provided samples for distribution. MDL Docket No. 1679, Ex. 12 at 75:7-78:4.

The evidence of Defendants' guilt related to their admitted fraud and off-label promotion scheme, coupled with the documented promotional visits by sales representatives, and testimony from Mr. Smith's prescribing medical providers, demonstrates that prescribers were influenced by Defendants' affirmative fraudulent promotion of Neurontin as safe and effective for treatment of pain, depression or anxiety — all off-label uses. *See In re Pharmaceutical Ind. Avg. Wholesale Price Litig.*, 252 F.R.D. 83, 99 (D. Mass. 2008) (where plaintiffs' damages were alleged to be caused by a lengthy course of prohibited conduct that affected a large number of consumers, the showing of reliance need not include direct evidence of reliance by individual consumers of defendants' products").

The evidence in this case demonstrates that Defendants fraudulently concealed the risks of adverse mood and behavior and an increased risk for suicidality from the ingestion of

Neurontin. Defendants did not provide safety information concerning the risks of suicidality from ingestion of Neurontin to any of Richard Smith's prescribing health care providers during any of the many visits from Defendants' pharmaceutical representatives or in the PDR or any promotional material provided in relation to Neurontin. The national marketing documents will demonstrate that Defendants, although they were aware of the risks, intentionally and fraudulently concealed same from Richard Smith's treating physicians. That Defendants had a plan and had prepared an elaborate scheme in order to suppress and/or fraudulently conceal the risks utilizing sales representatives, such as those who visited Mr. Smith's treating physicians.

POINT VI

**EVIDENCE OF OTHER LAWSUITS DEMONSTRATES THAT EVEN
THOUGH DEFENDANTS HAD AMPLE NOTICE OF SAFETY CONCERNS
WITH NEURONTIN THEY FAILED TO TAKE ADEQUATE MEASURE
TO PERFORM THE NECESSARY PHARMACOVIGILANCE, PROVIDE
THE OFF-LABEL USE POPULATION WITH WARNINGS REGARDING
THE RISKS OF SUICIDALITY AND INSTEAD CONTINUE TO
PERPETUATE THE BREACH OF THEIR DUTY OF CARE**

The cases Defendants cite to support the exclusion of other lawsuits are inapposite and do not apply in this case; they reference instances where the facts and circumstances of the lawsuits are not related to the case at hand or improperly based on prior unrelated lawsuits. Defendants' negligence in each case flows from the same facts and circumstances in regard to the issue of Defendants' breach of care. The fact that Defendants received additional knowledge from the filing of lawsuits that there were safety concerns and instead chose to sit on their hands rather than perform the required pharmacovigilance is further evidence of their reckless disregard for the safety of the off-label population. It was the FDA who performed the meta-analyses and mandated a new 2009 Neurontin label that provided off-label users with the information concerning an increased risk for suicide and that users should be monitored. Other lawsuits

provide evidence of Defendants' reckless indifference in breach of their duty of care for which the probative value substantially outweighs any potential for unfair prejudice to Defendants. Moreover, evidence concerning prior lawsuits are proper fodder for impeachment of witnesses pursuant to Fed. R. Evid. 613. *Wilson v. Scripps-Howard Broadcasting Co.* 642 F.2d 371, 376 (6th Cir. 1981) (in a libel case a rancher who testified to being surprised when a television station reported that he had starving cattle on his ranch his adversary evidence of other lawsuits which alleged that he mistreated animals was admitted to rebut the rancher's claim of surprise).

CONCLUSION

Plaintiff respectfully requests that this Court deny Defendants' Motion *in Limine* to exclude evidence of marketing or advertising materials and conduct, as these materials are relevant to Defendants' knowledge of the risks of Neurontin, duty of care, negligent and reckless disregard and punitive damages, and Plaintiff's claim of fraudulent concealment and suppression of the risks of Neurontin and their probative value greatly outweighs any alleged prejudice to Defendants by the admission of these documents into evidence.

Dated: April 27, 2010

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on this the 27th day of April, 2010, I electronically filed the foregoing document with the Clerk of the Court, United States District Court for the Middle District of Tennessee, using the CM/ECF system. True and correct copies of the foregoing documents are being served via the Court's CM/ECF system on the following:

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